CLAIM AMENDMENTS

1 to 122. *CANCELLED*

123. *(New)* A concentrated hormone composition for use in compounding a pharmaceutical product for topically delivering one or more steroid hormones to a subject in need of hormone replacement therapy, comprising:

a) one or more naturally occurring steroid hormone(s); and

b) a combination of penetration enhancing solvents that promotes delivery of the steroid hormone(s) through the dermis following topical administration;

with the proviso that the composition is essentially free of water; and

wherein the combination of penetration enhancing solvents comprises ethoxy diglycol and propylene glycol.

124. *(New)* The concentrated composition of claim 123, wherein the only solvents are ethoxy diglycol and propylene glycol.

125. *(New)* The concentrated composition of claim 123, wherein the solvents in the composition consist essentially of about 50% ethoxy diglycol and about 50% propylene glycol.

126. *(New)* The concentrated composition of claim 123, comprising one or more estrogen(s) at a total concentration of at least 40 mg per gram.

127. *(New)* The concentrated composition of claim 126, wherein said estrogen(s) are selected from the group consisting of estriol, estradiol, and estrone.

128. *(New)* The concentrated composition of claim 123, comprising at least one androgen at a concentration of at least 150 mg per gram.

129. *(New)* The concentrated composition of claim 128, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

130. *(New)* The concentrated composition of claim 123, comprising at least one progestagen at a concentration of at least 200 mg per gram.

131. *(New)* The concentrated composition of claim 130, wherein said progestagen is selected from progesterone and pregnenolone.

132. *(New)* A concentrated composition for use in compounding a pharmaceutical product for delivering hormones to a subject in need of hormone replacement therapy, comprising a plurality of different naturally occurring estrogens dissolved or suspended in one or more solvent(s) or wetting agent at a total concentration of least 6 mg of estrogens per gram.

133. *(New)* The concentrated composition of claim 132, wherein the total concentration of estrogens is between about 10 and 60 mg per gram.

134. *(New)* The concentrated composition of claim 132, wherein the composition comprises about 40 mg of estrogens per gram.

135. *(New)* The concentrated composition of claim 132, wherein the estrogens are selected from the group consisting of estriol,estradiol, and estrone.

136. *(New)* The concentrated composition of claim 135, wherein the ratio of estriol:estradiol by weight is 5:5, 6:4, 7:3, 8:2, or 9:1.

137. *(New)* The concentrated composition of claim 135, wherein the ratio of estriol, estradiol, and estrone by weight is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

138. *(New)* The concentrated composition of claim 132, wherein the solvents are a combination of ethoxy diglycol and propylene glycol.

139. *(Withdrawn) (New)* A method for preparing the concentrated composition of any of claims 123-138, comprising:

a) combining said steroid hormone(s) with said solvent(s) or wetting agent; and

b) processing said combination in an ointment mill or homogenizer to decrease particle size of said hormone(s) in the combination.

140. *(New)* A plurality of concentrated hormone compositions according to any of claims 123-138.

141. *(New)* A system for compounding pharmaceutical products for use in hormone replacement therapy,

wherein the system allows the product to be custom tailored for each individual consumer;

wherein the system comprises a plurality of concentrated hormone reagent compositions, each of which contains:

a) one or more steroid hormone(s); and

b) one or more penetration enhancing solvent(s) or wetting agents;

wherein said compositions are sufficiently concentrated so that they may be compounded into a pharmaceutical product each in an amount that is custom tailored to the needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

142. *(New)* The pharmaceutical compounding system of claim 141, wherein each concentrated reagent composition is contained in a graduated dispensing device.

143. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent cooption wherein the penetration enhancing solvents are ethoxy diglycol and propylene glycol.

144. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing one or more estrogen(s) at a total concentration of at least 40 mg per gram.

145. *(New)* The pharmaceutical compounding system of claim 144, wherein said estrogen(s) are selected from the group consisting of estriol, estradiol, and estrone.

146. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing a plurality of different estrogens at a total concentration of between 10 and 60 mg of estrogens per gram

147. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition containing at least one androgen at a concentration of at least 150 mg per gram.

148. *(New)* The pharmaceutical compounding system of claim 147, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

149. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition at least one progestagen at a concentration of at least 200 mg per gram.

150. *(New)* The pharmaceutical compounding system of claim 149, wherein said progestagen is selected from progesterone and pregnenolone.

151. *(New)* The pharmaceutical compounding system of claim 141, comprising a plurality of concentrated reagent compositions, each containing a different estrogen.

152. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition comprising estriol and a concentrated reagent composition comprising estradiol.

153. *(New)* The pharmaceutical compounding system of claim 141, comprising a concentrated reagent composition comprising estriol, a concentrated reagent comprising estradiol, and a concentrated reagent comprising estrone.

154. *(New)* The pharmaceutical compounding system of claim 141, wherein the concentrated reagent compositions can be compounded into a pharmaceutical product comprising a therapeutically effective amount of estriol, estradiol, and estrone at a ratio of 8:1:1, 5:4:1, 6:3:1, or 7:2:1 by weight.

155. *(New)* The pharmaceutical compounding system of any of claims 141-154, further comprising a separate reagent composition comprising a pharmaceutical carrier for combining with the concentrated reagent compositions to produce a pharmaceutical product formulated as an ointment, cream, gel, or paste.

156. *(New)* The pharmaceutical compounding system of any of claims 141-154, wherein each of said concentrated reagent compositions is color coded.

157. *(New)* The pharmaceutical compounding system of claim 156, wherein combination of some of said reagents into a particular pharmaceutical product produces a distinct color profile that can be used to confirm the identity of the hormone(s) in that product.

158. *(New)* A kit comprising the concentrated reagent compositions of the pharmaceutical compounding system of any of claims 141-154.

159. *(Withdrawn) (New)* A method for preparing the pharmaceutical compounding system of any of claims 141-154, comprising for each of said reagent compositions:

a) combining steroid hormone(s) with penetration enhancing solvent(s); and

b) processing said combination in an ointment mill or homogenizer to decrease particle size of said hormone(s) in the solvent(s).

160. *(New)* A method for compounding a pharmaceutical product for administering one or more hormones to a consumer in need of hormone replacement therapy, whereby the product is custom tailored for each individual consumer, the method comprising:

a) obtaining one or more concentrated reagent compositions, each comprising one or more steroid hormone(s) in one or more penetration enhancing solvent(s) or wetting agents;

b) ascertaining the needs of an individual consumer;

c) compounding one or more of said concentrated reagent composition(s) into said pharmaceutical product at a ratio that is custom tailored to the individual needs of said consumer, wherein the final concentration of each of said steroid hormone(s) in the pharmaceutical product is sufficient to be therapeutically effective for the consumer in accordance with their needs.

161. *(New)* The compounding method of claim 160, wherein the needs of each consumer are ascertained by way of a prescription from a doctor for replacement of particular hormone(s) each in a particular amount.

162. *(New)* The compounding method of claim 160, comprising combining a plurality of said concentrated reagent compositions such that the final concentration of the hormone(s) from each concentrated reagent composition in the pharmaceutical product is therapeutically effective for the consumer.

163. *(New)* The compounding method of claim 160, wherein concentrated reagent composition(s) are compounded with a suitable pharmaceutical carrier to produce a pharmaceutical product formulated as an ointment, cream, gel or paste.

164. *(New)* The compounding method of claim 160, wherein the penetration enhancing solvents are ethoxy diglycol and propylene glycol.

165. *(New)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains one or more estrogen(s) at a total concentration of at least 40 mg per gram.

166. *(New)* The compounding method of claim 165, wherein said estrogen(s) are selected from the group consisting of estriol, estradiol, and estrone.

167. *(New)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains a plurality of estrogen(s) at a total concentration of between 10 and 60 mg of estrogens per gram.

168. *(New)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one androgen at a concentration of at least 150 mg per gram.

169. *(New)* The compounding method of claim 168, wherein said androgen is selected from testosterone and dehydroepiandrosterone (DHEA).

170. *(New)* The compounding method of claim 160, wherein at least one of the concentrated reagent compositions contains at least one progestagen at a concentration of at least 200 mg per gram.

171. *(New)* The compounding method of claim 170, wherein said progestagen is selected from progesterone and pregnenolone.

172. *(New)* The compounding method of claim 160, comprising combining a plurality of concentrated reagent compositions, each containing a different estrogen.

173. *(New)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol and estradiol.

174. *(New)* The compounding method of claim 173, wherein the ratio of estriol:estradiol by weight in the final product is 5:5, 6:4, 7:3, 8:2, or 9:1.

175. *(New)* The compounding method of claim 160, whereby the pharmaceutical product produced contains estriol, estradiol, and estrone.

176. *(New)* The compounding method of claim 175, wherein the ratio of estriol, estradiol, and estrone by weight in the final product is 8:1:1, 5:4:1, 6:3:1, or 7:2:1.

177. *(New)* The compounding method of any of claims 160-176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying the identity of the hormone(s) in the product according to the color of the pharmaceutical product after compounding.

178. *(New)* The compounding method of any of claims 160-176, in which one or more of said concentrated reagent composition(s) is color coded, and the method further comprises verifying that the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

179. *(New)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a patient for replacement or supplementation of one or more hormone(s); and

b) prescribing for the patient a pharmaceutical product that is compounded according to the method of any of claims 160-176, whereby the product is customized to the individual needs of the subject determined in step a).

180. *(New)* A method of hormone replacement therapy, comprising:

a) ascertaining the individual needs of a consumer for replacement or supplementation of one or more hormone(s);

b) compounding a pharmaceutical product according to the method of any of claims 160-176, whereby the product is customized to the individual needs of the subject determined in step a); and

c) providing said pharmaceutical product to the consumer.

181. *(New)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded using the pharmaceutical production system of claim 156, comprising:

a) observing the color of the pharmaceutical product after compounding;

b) deducing the identity of the hormone(s) in the product from the color; and

c) comparing the hormone(s) in the product with the hormone(s) that need supplementation in a particular consumer.

182. *(New)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 177, comprising:

a) observing the color of the pharmaceutical product after compounding;

b) deducing the identity of the hormone(s) in the product from the color; and

c) comparing the hormone(s) in the product with the hormone(s) that need supplementation in a particular consumer.

183. *(New)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded using the pharmaceutical production system of claim 156, comprising determining whether the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.

184. *(New)* A method of quality control of a pharmaceutical product intended for hormone replacement therapy that was compounded according to the method of claim 178, comprising determining whether the ingredients of the product have been adequately mixed according to whether the final product is a uniform color throughout.